

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENZYME CORPORATION and)	
AVENTIS INC.,)	
)	
Plaintiffs,)	
)	
v,)	
)	C.A. No. 23-cv-0554 (RGA)
NOVARTIS GENE THERAPIES, INC. and)	
NOVARTIS PHARMACEUTICALS)	JURY TRIAL DEMANDED
CORPORATION)	
)	
Defendants.)	
)	

STIPULATED PROTECTIVE ORDER

WHEREAS discovery in the above-captioned proceeding (the “Action”) may involve the disclosure of certain documents, things, and information in the possession, custody, or control of Plaintiffs Genzyme Corporation and Aventis Inc. and Defendants Novartis Gene Therapies, Inc. and Novartis Pharmaceutical Corporation, or other persons that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development, or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure;

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

WHEREAS the parties have, through counsel, stipulated to the entry of this Protective Order (“Protective Order”) for the purpose of advancing the progress of this Action and to prevent unnecessary dissemination or disclosure of such trade secret, confidential, or proprietary information; and

WHEREAS the parties have established good cause for entry of this Protective Order;

Therefore, the following provisions of this Order shall control the disclosure, dissemination, and use of information in this Action:

SCOPE

1. This Protective Order shall apply to all documents, records, correspondence between counsel, depositions, pleadings, exhibits, and all other material or information subject to discovery in this Action, including responses to requests for production of documents, answers to interrogatories, responses to requests for admissions, deposition testimony, expert testimony and reports, and all other discovery taken pursuant to the Federal Rules of Civil Procedure, matters in evidence, and any other information hereafter furnished, directly or indirectly, by or on behalf of any party, non-party, or witness in connection with this Action (collectively, “Discovery Material”).

2. As used herein, “Producing Party” shall refer to any party to this Action and to any non-party who produces Discovery Material, and “Receiving Party” shall refer to any individual or entity who properly receives, is shown, or is exposed to Discovery Material according to this Protective Order.

3. This Protective Order shall apply to the parties and any non-party from whom discovery may be sought and who desires protection under this Protective Order.

DESIGNATION

4. Any Producing Party may designate Discovery Material as “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY” (hereinafter, “Designated Information”) in accordance with this Protective Order if such party in good faith believes that such Discovery Material contains HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information as defined in Paragraph 5 or Paragraph 6, respectively. The burden of establishing that Discovery Material is

HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY as defined herein shall be on the Producing Party. The designation of any Discovery Material as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY shall be deemed effective unless and until the Court orders otherwise or the Producing Party withdraws the designation.

5. HIGHLY CONFIDENTIAL Discovery Material shall mean Discovery Material that a Producing Party in good faith claims to constitute or contain (i) confidential research; (ii) confidential development, manufacturing, regulatory, financial, commercial, marketing, or business information of a technical or non-technical nature; (iii) trade secrets, know how, or proprietary data relating to research, development, manufacturing, regulatory, financial, commercial, marketing, or business subject matter of a technical or non-technical nature; (iv) any other information or materials the disclosure of which is likely to harm the competitive position of the Producing Party, or the disclosure of which would contravene an obligation of confidentiality to a third person or to a Court; (v) any health information protected under state or federal privacy laws, including information that a party is required to maintain in confidence under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”); (vi) information or materials protected from disclosure by foreign Data Protection Laws or other privacy obligations or other applicable foreign law; and (vii) information or materials which the Producing Party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure. The Discovery Material will be marked by the Producing Party with the following legend: “HIGHLY CONFIDENTIAL.”

6. HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY Discovery Material shall mean HIGHLY CONFIDENTIAL Discovery Material as set forth in Paragraph 5

that a Producing Party in good faith claims to constitute or contain highly sensitive information or items that are current or future business or technical trade secrets and plans more sensitive or strategic than HIGHLY CONFIDENTIAL information, the disclosure of which is likely to significantly harm that person's and/or the Producing Party's competitive position, or the disclosure of which would contravene an obligation of confidentiality to a third person or to a Court. Examples of "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" information or tangible things include, without limitation, trade secrets, non-public financial information, business and sales strategies, product roadmaps, ongoing research and development materials, sensitive technical materials, and other information of a similar nature. The Discovery Material will be marked by the Producing Party with the following legend: "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY."

7. Information to be treated under this Protective Order as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY shall include but not be limited to:

a. Information set forth in discovery requests or responses made under Fed. R. Civ. P. 31, 33, or 36, or in documents produced, for example under Fed. R. Civ. P. 33(d) or 34 or pursuant to the Delaware Default Standard for Discovery, provided that, prior to delivery to the Receiving Party, the responses or copies of documents are marked by the Producing Party as "HIGHLY CONFIDENTIAL" or "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" in accordance with Paragraph 5 or Paragraph 6.

b. Information revealed by inspection of things and premises under Fed. R. Civ. P. 34. Such information will be treated as HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY until the Discovery Material is produced and marked in accordance

with Paragraphs 5 or 6 as determined by the Producing Party. There will be no waiver of confidentiality by the inspection of Designated Information before it is copied and marked pursuant to this Order. Unless otherwise agreed by the Producing Party, inspection of Discovery Material by any party may only be conducted by persons eligible under Paragraph 15(a) below.

c. Information revealed during a deposition upon oral or written examination under Fed. R. Civ. P. 30. Such information shall be considered HIGHLY CONFIDENTIAL for thirty (30) calendar days following receipt of the final transcript by counsel for the Producing Party, but not thereafter unless, before the thirty (30) calendar day period has expired, counsel for the Producing Party notifies counsel for the Receiving Party in writing that Designated Information is set forth in the transcript, or during the deposition, counsel for the Producing Party or any other party designates the transcript as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY Discovery Material. The legend described in Paragraph 5 or Paragraph 6 shall be placed on the front of any deposition transcript (and, if videotaped, any copies of the videotape) containing HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY Designated Information.

d. Copies, extracts, and complete or partial summaries prepared from HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information, as well as portions of briefs, memoranda, or any other writings filed with the Court and exhibits that contain, summarize, or reflect the content of any HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information, that are prominently marked as containing HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information.

8. Nothing in this Order prevents a party or a third-party from redacting, from otherwise discoverable information or things, information that (i) is protected under state or federal privacy laws, or foreign Data Protection Laws or other privacy obligations, (ii) is neither relevant to any party's claim or defense nor proportional to the needs of this litigation, or (iii) is subject to the attorney-client privilege, work-product immunity, or any other applicable privilege. Each such redaction shall be clearly labeled as redacted accompanied by an appropriate legend describing the reason for the redaction. This paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information.

USE

9. Designated Information under this Protective Order may be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the Receiving Parties to any party or person not entitled under this Protective Order to have access to such material, and shall be used by the Receiving Parties only for purposes of this Action and any appeal therefrom, and shall not be used for any other purpose including, but not limited to: research, development, manufacturing, financial, commercial, business, marketing, governmental, regulatory, competitive, or legal purpose (except for settlement of the above-captioned case or other proceedings as set forth in this Protective Order); any other litigation, arbitration, or claim (except as a court finds the information to be relevant and subject to disclosure in another case); in connection with the preparation or prosecution of any patent application; or in any invalidity, opposition, inter partes review, reissue, or reexamination proceedings. Absent consent of the Producing Party and/or further order of this Court, all persons receiving or having access to information designated HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY are expressly prohibited from using or disclosing such information in connection with any practice before, or communication with, the United States

Patent and Trademark Office, the FDA (including in any Citizen Petition or controlled correspondence), the United States Pharmacopoeia, or their respective counterpart organizations in any foreign jurisdiction.

10. a. No individual receiving information designated HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY under this Protective Order from another Party in this Action shall use that HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information in any manner inconsistent with this Protective Order, including in connection with (i) the drafting or editing of any patent application (foreign or domestic) claim or claim amendment or (ii) the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition).

b. Absent consent of the Producing Party and/or further order of this Court, all individuals receiving information designated HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY under this Protective Order from a Producing Party in this Action, shall not, thereafter during the course of this Action and continuing for two years following final termination of this Action, work on or participate in directly or indirectly (i) the drafting, editing, or amending of any patent application (foreign or domestic) claim or claim amendment that is directed to (1) any treatment for spinal muscle atrophy (including any rAAV vector for such treatment), including without limitation the uses of any product for treatment for spinal muscle atrophy containing rAAV vectors or the method of manufacturing, and/or formulating any product for treatment for spinal muscle atrophy containing rAAV vectors, and/or (2) analytical ultracentrifugation of rAAV viral particles; or (ii) the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning any

product for treatment of spinal muscle atrophy (including any containing rAAV vectors for such treatment), including without limitation the uses of any product for treatment for spinal muscle atrophy containing rAAV vectors or the method of manufacturing and/or formulating any product for treatment for spinal muscle atrophy containing rAAV vectors.

c. Absent consent of the Producing Party and/or further order of this Court, all individuals designated under Paragraph 14(a) and 15(a) of this Protective Order receiving information designated HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY under this Protective Order from a Producing Party in this Action relating to the categories (1) conditions and/or materials of cell culture, transfection, harvesting, and purification; equipment used in the process; and production process through to finished drug product; (2) intermediate solutions and their compositions; (3) chemistry, manufacturing, and controls of elements of the plasmid used for transfection and of elements of cell banks; (4) assays used (including but not limited to quality control, quality assurance, and characterization of testing profiles for materials through to finished drug product); or (5) analytical ultracentrifugation of rAAV viral particles shall not, thereafter during the course of this Action and continuing for two years following final termination of this Action, work on or participate in directly or indirectly (i) the drafting, editing, or amending of any patent application (foreign or domestic) claim or claim amendment that is directed to a category of information above as it relates to any rAAV vector; or (ii) the drafting or editing of a Citizen Petition (or related submission, including a response to a Citizen Petition) concerning a category of information above as it relates to any rAAV vector. To the extent an individual does not receive information in any of the categories identified above, the bar shall not prohibit that individual from working on or participating directly or indirectly in prosecution or a Citizen Petition, so long as such individual

does not use any HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information received from another party in connection with any submissions.

d. For clarity, nothing in this paragraph shall prevent an individual who receives HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information from working on or participating in directly or indirectly (a) inter partes reviews, post grant reviews, or re-issue or re-examination proceedings at the U.S. Patent and Trademark Office or the Patent Trial and Appeal Board related to rAAV vectors, or (b) pre- or post-grant opposition proceedings or invalidation request proceedings before a foreign patent office or court related to rAAV vectors, so long as the individual does not work on or participate in directly or indirectly the drafting or editing of a claim or claim amendment as described in this paragraph. For further clarity, nothing in this paragraph shall prevent an individual who receives HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information from working on or participating directly or indirectly in the drafting or editing of submissions to the FDA that are not Citizen Petitions or related submissions, so long as such individual does not use any HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information received from another party in connection with such submissions.

e. The Parties expressly agree that the prosecution bar set forth herein shall be personal to any person who reviews HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information and shall not be imputed to any other persons or attorneys at the party’s law firm or company.

11. Nothing in this Protective Order shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to this Action and, in the course thereof, relying in a general way upon his or her examination of Designated Information produced or exchanged in this Action; provided, however, that in rendering such advice and in otherwise communicating with a person not entitled to access Designated Information, the attorney shall not disclose the contents of Designated Information produced by any other party or non-party to anyone not authorized under this Protective Order to receive the Designated Information.

12. Non-parties may designate as HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY deposition transcripts of their witnesses and any documents or information they produce, whether voluntarily or by subpoena, to the same extent and in the same manner as parties to this Action and any such Designated Information shall be treated by the parties to this Action in the same manner as Designated Information so designated by a party. Non-parties shall have the same rights and obligations under this Protective Order as parties and may move the Court to enforce the provisions of this Protective Order.

13. Nothing in this Protective Order precludes a Producing Party from using or disseminating its own Designated Information.

DISCLOSURE

14. Discovery Material designated as HIGHLY CONFIDENTIAL may be disclosed by the Receiving Party only to the following persons:

a. up to two (2) in-house attorneys who are licensed to practice law in the United States or other legal department personnel employed by a party with responsibility for overseeing the above-captioned litigation (and their clerical staffs, including paralegals and scientific advisors) and who have a need to know such information to fulfill their duties and

responsibilities in connection with this Action, subject to the requirements and procedures of Paragraphs 17 through 18.

- b. Counsel of Record for a party in this Action and employees of such counsel;
- c. independent experts/consultants and their staff, excluding current directors, officers, or employees of the parties and excluding fact deponents or witnesses in this Action except as permitted under Paragraph 19 below, retained to assist counsel for the parties in the conduct of this Action, subject to the requirements and procedures of Paragraphs 17 through 18;
- d. fact deponents or witnesses in this Action, subject to the requirements and procedures of Paragraph 19;
- e. the Court (including all appropriate courts of appellate jurisdiction) and its employees;
- f. court reporters, videographers, translators, or interpreters transcribing, recording, or translating testimony or documents, and their respective staffs employed in connection with this Action;
- g. professional vendors; and
- h. others as to whom the Producing Party has given written consent, subject to the requirements and procedures of Paragraphs 17 through 18.

15. Discovery Material designated as HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY may be disclosed by the Receiving Party only to the following persons:

- a. Counsel of Record for a party in this Action and employees of such counsel;
- b. independent experts/consultants and their staff, excluding current directors, officers, or employees of the parties and excluding fact deponents or witnesses in this Action

except as permitted under Paragraph 19 below, retained to assist counsel for the parties in the conduct of this Action, subject to the requirements and procedures of Paragraphs 17 through 18;

c. fact deponents or witnesses in this Action, subject to the requirements and procedures of Paragraph 19;

d. the Court (including all appropriate courts of appellate jurisdiction) and its employees;

e. court reporters, videographers, translators, or interpreters transcribing, recording, or translating testimony or documents, and their respective staffs employed in connection with this Action;

f. professional vendors; and

g. others as to whom the Producing Party has given written consent, subject to the requirements and procedures of Paragraphs 17 through 18.

16. In the event that one of the aforementioned in-house attorneys identified in Paragraph 14(a) ceases to have responsibilities relating to this litigation, a party may designate another in-house person who otherwise qualifies under the provisions of Paragraph 14(a) to replace such person, according to the requirements and procedures of Paragraphs 17 through 18.

17. No person identified in Paragraph 14(a) (*e.g.*, in-house attorneys), Paragraph 14(c) or 15(b) (*e.g.*, experts), or Paragraph 14(h) or 15(g) (*i.e.*, other permitted persons) shall be provided access to Designated Information unless such person has first signed the *Declaration of Compliance* attached to this Protective Order as Exhibit A, and agreed to be subject to the jurisdiction of the Court for any proceedings concerning compliance or alleged noncompliance with this Order.

18. The procedure for disclosing Designated Information to a person identified in Paragraphs 14(a) (*e.g.*, in-house attorneys), Paragraph 14(c) or 15(b) (*e.g.*, experts), or Paragraph 14(h) or 15(g) (*i.e.*, other permitted persons) shall proceed according to the following sub-paragraphs. Clerical support staff for such identified persons are exempt from the notification requirement of this paragraph and sub-paragraphs.

a. The disclosing party shall notify the Producing Party by email of the intended disclosure accompanied by a copy of the *Declaration of Compliance* signed by the intended recipient. For a person identified in Paragraph 14(c) or 15(b) (*e.g.*, an expert), the disclosing party shall further simultaneously provide a current *curriculum vitae* or equivalent resume disclosing the individual's employment history, any past or present relationship with any of the parties, all consulting engagements during the past five (5) years (the existence of which is not itself confidential), and an identification (by name and number of the case and location of court) of any litigation in connection with which the individual has testified as an expert during the previous five (5) years at trial or by deposition.

b. The disclosing party shall not disclose any Designated Information to a person identified in Paragraphs 14(a) (*e.g.*, in-house attorneys), Paragraph 14(c) or 15(b) (*e.g.*, experts), or Paragraph 14(h) or 15(g) (*i.e.*, other permitted persons) for a period of seven (7) calendar days following the email notification and disclosure described in Paragraph 18(a).

c. During the seven-day period, the Producing Party may object to the intended disclosure. Any objection to the disclosure must be transmitted by email and must include the legal and factual basis for the objection and all supporting documentation.

d. The parties shall meet and confer in good faith by telephone to attempt to resolve the objection within five (5) business days following the email notice of the objection.

e. If the parties cannot resolve the objection within the five-day period following the email notice of the objection, the Producing Party, within five (5) business days thereafter, shall initiate the procedures prescribed by Section 3(g) of the Joint Scheduling Order (D.I. 28), “Discovery Matters and Disputes Relating to Protective Order,” to obtain judicial resolution of the objection. The burden shall be on the Producing Party to demonstrate to the Court why the proposed disclosure should not be made.

f. If the Producing Party does not timely initiate such procedures, the Producing Party waives its objection to the disclosure and the disclosing party is free to disclose the Designated Information to the identified person. If the Producing Party initiates such procedures within the five-day period, the disclosing party shall not disclose the Designated Information to the identified person until the objection is resolved, either by the parties or the Court. The disclosing party may seek to modify the scheduling order to prevent prejudice resulting from delayed or denied disclosure.

19. During the course of preparing for a deposition or testimony, or during a deposition or testimony, a fact deponent or witness may not be shown Designated Information, unless:

a. the fact deponent or witness is otherwise entitled to view the Designated Information under this Protective Order;

b. the fact deponent or witness is a current employee or corporate representative of the Producing Party, and the Designated Information was not obtained solely from another party to this Action;

c. the Producing Party is showing its own Designated Information to a deponent or witness representing or currently affiliated with the Producing Party, and the Designated Information was not obtained solely from another party to this Action.

d. the Designated Information reveals on its face that the deponent or witness authored the Designated Information or received the Designated Information in the ordinary course of business and outside the context of this Action; or

e. foundation testimony or other Discovery Material establishes that the deponent or witness is the author of such Designated Information, is otherwise familiar with the content of the Designated Information, or would have had access to or received the Designated Information in the ordinary course of business or as part of their normal duties and outside the context of this Action.

20. Any document, pleading, or tangible item containing Designated Information that is filed or submitted to the Court shall be properly designated as provided in this Protective Order and filed under seal pursuant to the provisions of the Local Rules of the Court.

21. If a party intends to disclose the Designated Information of another party during a trial, court appearance, or hearing that is open to the public, the disclosing party shall notify the Producing Party and make an application to the Court to permit such use, unless consent from the Producing Party is previously obtained.

22. The recipient of any Designated Information that is provided under this Protective Order shall maintain such information in a secure and safe area and shall exercise reasonable and proper care with respect to the storage, custody, use, and/or dissemination of such information.

23. All Designated Information shall be protected from disclosure as specified herein, unless a party obtains an Order of the Court declaring that all or certain portions of such Designated Information are not, in fact, protected or the Producing Party agrees in writing to modify or rescind such designation.

INADVERTENT PRODUCTION/DESIGNATION

24. The inadvertent failure by a party to designate Discovery Material as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY shall not be a waiver of such designation provided that the party who fails to make such designation informs the Receiving Party that such Discovery Material is HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY within seven (7) business days from when the inadvertent failure to designate first became known to the designating party. Failure to act within the seven (7) business day period shall not preclude the designating party from later initiating procedures with the Court to impose such a designation.

25. A party receiving Discovery Material that a Producing Party inadvertently failed to designate as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY shall not be in breach of this Order for any use made of such Discovery Material or any permitted disclosures of such Discovery Material made prior to being informed of the inadvertent failure to designate. Once the Receiving Party has been informed of the inadvertent failure to designate pursuant to Paragraph 24, the Receiving Party shall take reasonable steps to, at the Producing Party’s option, either ensure that all copies of any such Discovery Material are returned promptly to the Producing Party or ensure that all copies of any such Discovery Material are marked with the proper designation and distributed only as permitted under this Protective Order. In the case of produced documents, the Producing Party shall, separately from any other production, reproduce the documents with the correct designation, unless the Receiving Party agrees to waive the reproduction.

UNAUTHORIZED DISCLOSURE

26. Except for the circumstances described in Paragraph 25, in the event of disclosure of Designated Information to any unauthorized person, whether the result of inadvertent disclosure or other causes, the disclosing party, and each party with knowledge thereof, shall immediately inform the Producing Party of all known relevant information concerning the nature and circumstances of the disclosure. The party responsible for improperly disclosing such Designated Information shall also promptly take all reasonable measures to retrieve the Designated Information and to ensure that no further or greater unauthorized disclosure and/or use thereof is made. Such unauthorized disclosure shall not be a waiver of any of the Producing Party's attorney-client privilege, work-product immunity, or any other privilege or immunity belonging to the Producing Party.

OBJECTIONS TO DESIGNATIONS

27. Any party may object to a designation and seek to remove the confidentiality restrictions set forth herein on the ground that Designated Information does not fall within the definition of HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY set forth in Paragraphs 5 and 6 above, respectively. The process for making such an objection and for resolving the dispute shall be as follows:

a. The objecting party shall notify the Producing Party in writing as to its objection(s) to the designations. This notice shall include, at a minimum, a specific identification of the Designated Information objected to as well as the reason(s) for the objection.

b. The objecting party shall thereafter confer either in person or by telephone with the Producing Party claiming protection (as well as any other interested party) within five (5) business days in a good faith effort to resolve the dispute.

c. If the parties cannot reach agreement concerning the matter within seven (7) business days after the delivery and receipt of the notice, the objecting party may initiate procedures with the Court seeking a ruling that the Designated Information is not entitled to such designation, as outlined in the Court's rules regarding Discovery Dispute Resolution. The Producing Party shall bear the burden to establish that the Discovery Material is HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY and entitled to protection under this Protective Order.

28. Notwithstanding any such challenge to Designated Information, all such Discovery Material shall be treated as Designated Information and shall be subject to the provisions of this Protective Order until one of the following occurs: (i) the party who designated the material as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY withdraws such designation in writing, or (ii) the Court rules that the designation is not proper and that the designation be removed.

PRIVILEGED & PROTECTED DISCOVERY MATERIALS

29. With respect to information generated after the filing of the complaint, parties are not required to include any such information in privilege logs.

30. Any party withholding information on the basis of a claim of attorney-client privilege, work product, or any other privilege or immunity shall abide by the requirements of Fed. R. Civ. P. 26(b)(5)(A). The parties will confer on the nature and scope of privilege logs for the case, including whether categories of information may be excluded from any logging requirements and whether alternatives to document-by-document logs can be exchanged.

31. Pursuant to Federal Rule of Evidence 502(b), the inadvertent production of information subject to a claim of attorney-client privilege, work product, or any other privilege or immunity will not waive the claim of attorney-client privilege, work product, or any other privilege

or immunity. In addition, the fact that information was inadvertently produced shall not be used in any manner as evidence in support of any such alleged waiver.

32. If a party has inadvertently produced information subject to a claim of attorney-client privilege, work product, or any other privilege or immunity, after recognizing that privileged information has been produced or disclosed, the Producing Party shall notify the Receiving Party in writing of the inadvertent disclosure and the basis for the claim within seven (7) calendar days of discovery of the inadvertent disclosure. The Receiving Party shall return, sequester, or destroy the inadvertently produced information and all copies within five (5) business days of the notification. Moreover, any notes or summaries, other than those expressly permitted under this paragraph, referring to or relating to any such inadvertently produced information shall be sequestered or destroyed. Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, address(es), and such other information as is reasonably necessary to identify the information and generally describe its nature to the Court in any request to compel production thereof. Such a record of the identity and nature of the information may not be used for any purpose other than preparation of a request to compel in this Action. Without nullifying the Receiving Party's duty to return, sequester, or destroy inadvertently produced information, the Receiving Party may challenge the Producing Party's claim(s) of privilege or work-product by initiating procedures with the Court as outlined in Section 3(g) of the Joint Scheduling Order (D.I. 28), "Discovery Matters and Disputes Relating to Protective Orders," within twenty (20) calendar days of receiving notice that the information was inadvertently produced. Nothing in this paragraph shall restrict the rights of any party under Fed. R. Civ. P. 26(b)(5)(B).

33. Notwithstanding anything contained herein, the Producing Party may request the return of any document or thing under this section that has previously been used as an exhibit in any deposition without objection by the Producing Party only if such a request is made within five (5) business days after the document or thing was first used as an exhibit at a deposition. After such time period, and only to the extent allowed under Paragraph 32, and only to the extent that no questions were asked about, and no testimony was given regarding, the portion of the document the Producing Party claims privilege over, the Producing Party may provide a redacted version of the document, redacting only those portions of the document the Producing Party claims privilege over. Within five (5) business days of receiving such redacted version, the Receiving Party shall return to the Producing Party, or confirm in writing the destruction of, all inadvertently produced, unredacted versions of the document. The Receiving Party may challenge the Producing Party's claim(s) of privilege or work product under Paragraph 32, *supra*.

EXEMPTED MATERIALS

34. None of the provisions of this Protective Order shall prevent a Receiving Party from using or disclosing any Discovery Material or Designated Information that (i) is publicly known through no unauthorized act of the Receiving Party; (ii) is shown by written evidence to have been independently developed or known by the Receiving Party, prior to its production herein without use or benefit of the Discovery Material or Designated Information; or (iii) was lawfully obtained by the Receiving Party, other than through discovery of the Producing Party, without an understanding that the Discovery Material or Designated Information would be kept confidential. The Receiving Party shall have the burden of establishing through written evidence that such Discovery Material or Designated Information is publicly known, was independently developed or known prior to production by the Producing Party and without the benefit of the Discovery

Material or Designated Information, or was lawfully obtained other than through discovery from the Producing Party without an understanding that the Discovery Material or Designated Information would be kept confidential.

35. This Protective Order shall not apply to and, thus, does not restrict any party's use, for any purpose, of its own Designated Information, or to documents or other information that such party lawfully obtained prior to the entry of this Protective Order (unless subject to Delaware Local Rule 26.2). Moreover, this Protective Order shall not apply to and does not restrict any individual from reviewing or seeing any document authored, in whole or in part, by that individual.

36. This Protective Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work-product immunity, or to preclude either party from seeking further relief or protective orders from the Court as may be appropriate under the Federal Rules of Civil Procedure or any local rule.

RETURN/DESTRUCTION OF MATERIALS

37. Not later than ninety (90) calendar days after the final termination of this Action, whether by judgment and exhaustion of all appeals, by dismissal (with or without prejudice), or by settlement, unless otherwise agreed to in writing by an attorney of record for the designating party, (i) any Designated Information that resides in tangible form (*e.g.*, paper documents), including all copies, extracts, and summaries thereof, shall be returned to the Producing Party or destroyed, such election to be made by the Receiving Party, and (ii) any Designated Information that resides in electronic form shall be deleted from active memory and any other immediately available electronic storage media. The parties and their respective representatives, attorneys, experts, consultants, and litigation support services providers shall thereafter be prohibited from restoring such deleted electronic files. The parties, however, shall not be required to remove Designated Information that resides in electronic form on media that is maintained in the usual

course of business primarily for archival and disaster recovery purposes. The parties may continue to preserve such Designated Information maintained on archival/disaster recovery media in accordance with this Order until such archival/disaster recovery media is overwritten or destroyed in the usual course of business. Notwithstanding any of the foregoing, outside counsel for the parties shall be permitted to retain copies of all pleadings, work product, written discovery, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, and papers filed with the Court containing Designated Information for archival purposes. Such counsel and their employees, however, shall not disclose any Producing Party's Designated Information contained therein to any person or entity except pursuant to a written agreement with the Producing Party or as otherwise provided in this Protective Order. Not later than ninety (90) calendar days after the final termination of this Action, the Receiving Party shall certify in writing that all Designated Information has been returned or destroyed in accordance with this Paragraph.

MISCELLANEOUS PROVISIONS

38. This Protective Order is without prejudice to the right of any Producing Party to seek further or additional protection of information for which the protection of this Order is not believed by such party to be adequate. Nothing in this Protective Order shall be deemed to bar or preclude any Producing Party from seeking such additional protection, including, without limitation, an Order that certain information may not be discovered at all.

39. By entering this Protective Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Protective Order who becomes subject to a motion to disclose another party's information designated as HIGHLY CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY pursuant to this Protective Order shall promptly notify that party of the motion so that the

party may have an opportunity to appear and be heard on whether that information should be disclosed.

40. Nothing herein shall prevent disclosure beyond the terms of this Protective Order if the Producing Party explicitly consents to such disclosure in writing or on a transcribed record; or if the Court, after notice to all affected parties, orders or permits such disclosure.

41. The entry of this Protective Order shall not be construed as a waiver of any right to object to the furnishing of information in response to discovery and, except as expressly provided, shall not relieve any party of the obligation of producing information in the course of discovery.

42. If at any time Designated Information is subpoenaed by any court, arbitral, administrative, or legislative body, the party or person to whom the subpoena or other request is directed shall promptly give written notice thereof to counsel for the Producing Party and shall provide the Producing Party an opportunity to object to the production of such Designated Information. If the Producing Party does not move for a protective order within fourteen (14) calendar days of the date written notice is given, or before the return date of the subpoena if less than fourteen (14) calendar days from the date written notice is given, the party or person to whom the referenced subpoena is directed may produce the Designated Information on or after the date set for production in the subpoena.

43. Counsel for any party to this Protective Order shall have the right to exclude from depositions any individual, other than the deponent and the reporter, who is not authorized under this Protective Order to receive Discovery Material designated as HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY. Such right of exclusion shall be applicable only during periods of examination or testimony directed to HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY

Designated Information other than Designated Information produced by the party with which the individual is currently affiliated. The failure of unauthorized individuals to leave the deposition room during any portion of the deposition which inquires into matters deemed HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY by a Producing Party other than one with which the individual is currently affiliated shall constitute justification for counsel to instruct the deponent that he or she should not answer a question concerning HIGHLY CONFIDENTIAL and/or HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY information.

44. All notices required by this Protective Order are to be made by email to counsel representing the noticed party. For a notice received pursuant to the requirements of this Protective Order, the date by which the receiving party shall respond or otherwise take action shall be computed from the date of receipt of the notice, and any notice required under the provisions of this Protective Order and sent after 5:00 p.m. Eastern Time shall be considered as received not earlier than the next business day. Any of the notice requirements herein may be waived in whole or in part, but only in a writing signed by an attorney for the party granting the waiver.

45. Execution of this Protective Order shall not constitute a waiver of the right of any party to claim in this Action or otherwise that any documents, communications, or any portion thereof, are privileged or otherwise non-discoverable, or are not admissible in evidence in this Action or any other proceeding.

46. Each person or entity who receives Designated Information agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Protective Order.

47. Nothing in this Order shall prevent a party from using any Designated Information at a hearing, trial, or other proceeding in this Action. The parties shall take all steps permitted and/or ordered by the Court and reasonably required to protect the confidentiality of such Designated Information during such use. Designated Information shall not lose its confidential status through such use, unless used in a proceeding open to the public.

48. This Protective Order shall survive the termination of this Action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court and so ordered by the Court.

49. All documents produced in this Action as “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL EYES ONLY PURSUANT TO DEL. L.R. 26.2” prior to the entry of this Protective Order will be treated as if designated HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY and subject to the provisions of this Protective Order.

50. Upon filing this Protective Order with the Court, the parties agree to treat it as “So Ordered,” subject to any future modifications by agreement of the parties or by the Court.

SO ORDERED this 26 day of July, 2023.

/s/ Richard G. Andrews

United States District Court Judge

Dated: July 25, 2023

/s/ Scott B. Czerwonka

David E. Wilks (Del. Bar #2793)
Scott B. Czerwonka (Del. Bar #4844)
WILKS LAW, LLC
4250 Lancaster Pike, Suite 200
Wilmington, DE 19085
(302) 225-0858
dwilks@wilks.law
sczerwonka@wilks.law

OF COUNSEL:

Katherine A. Helm
Noah M. Leibowitz
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
(212) 698-3500
khelm@dechert.com
noah.leibowitz@dechert.com

Martin J. Black
Sharon K. Gagliardi
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000
martin.black@dechert.com
sharon.gagliardi@dechert.com

Jonathan D.J. Loeb
DECHERT LLP
3000 El Camino Real Five Palo Alto Sq.
Suite 650
Palo Alto, CA 94306
(650) 813-4800
jonathan.loeb@dechert.com

Amanda K. Antons
DECHERT LLP
35 W. Wacker Drive,
Suite 3400

/s/ Alexandra M. Joyce

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

OF COUNSEL:

John Livingstone
M. David Weingarten, Ph.D.
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
271 17th Street, NW, Suite 1400
Atlanta, GA 30363-6209
(404) 653.6449
john.Livingstone@finnegan.com
david.weingarten@finnegan.com

Cora Holt
Christopher W. Weber, Ph.D.
Aida Liman-Tingui
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408.4153
cora.holt@finnegan.com
christopher.weber@finnegan.com
aida.liman-tingui@finnegan.com

Jeffrey D. Smyth
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER LLP
3300 Hillview Avenue, 2nd Floor
Palo Alto, CA 94304-1203
(605) 849.6600
jeffrey.smyth@finnegan.com

Attorneys for Defendants Novartis Gene

Chicago, IL 60601
(312) 646-5800
amanda.antons@dechert.com

*Therapies, Inc. and Novartis Pharmaceuticals
Corp.*

*Attorneys for Plaintiffs Genzyme Corporation
and Aventis Inc.*

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GENZYME CORPORATION and
AVENTIS INC.,

Plaintiffs,

 $V,$

NOVARTIS GENE THERAPIES, INC. and
NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendants.

C.A. No. 23-0554 (RGA)

JURY TRIAL DEMANDED

DECLARATION OF COMPLIANCE

I, _____ declare and state as follows:

I live at _____.

I am employed as a _____ (state position) by _____
 _____ (state name and address of employer).

I have read the Protective Order entered in this case, a copy of which has been given to me. I understand and agree to comply with and be bound by the provisions of the Protective Order, including that upon receipt of any Highly Confidential and/or Highly Confidential – Outside Attorneys’ Eyes Only information, I will be personally subject to the Protective Order, and to all of its requirements and procedures.

At the final termination of these litigations, I will destroy or return to counsel all documents or things consisting of or containing Highly Confidential and/or Highly Confidential – Outside Attorneys’ Eyes Only information.

_____ By initialing here, I further state that I am an in-house attorney or other legal department personnel employed by a party to these litigations, or a parent or subsidiary to a party to these

litigations and identify myself as an authorized in-house recipient of Highly Confidential information according to the provisions of Paragraph 14(a) of the Protective Order.

I declare, as provided by 28 U.S.C. Section 1746, under penalty of perjury under the laws of the United States of America, that the foregoing is true and connect.

Signature: _____

Executed: _____
(date)